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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,698	01/23/2002	Tatsuki Shiota	Q68142	8252
23373 7590 01/26/2007 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER WANG, SHENGJUN	
			ART UNIT	PAPER NUMBER
			1617	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/26/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/031,698

Applicant(s)

SHIOTA ET AL.

Examiner

Shengjun Wang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7 and 11-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7 and 11-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 30, 2006 has been entered.
2. The elected compound 2296, which featured as R4 or R5 is (CH₂)₂SO₂CH₃, is found allowable, as the prior art provides no sufficient guidance to reach the compound with CCR-3 inhibiting activity. The search has been extended and the claims are rejected as follow

Claim Rejections 35 U.S.C. 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7, 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rogers et al. (WO 0031032, IDS 02/23/2005).

Rogers teaches pyrrolidine derivatives-CCR-3 receptor antagonist with a general formula I, wherein Z may be N, A may be -NCO-, B is alkylene with 1-4 carbon inclusive wherein one of the carbon atom may optionally be replaced by -N(R₄)-, -NR₂C(O)NR₃-, etc., Ar₁ and Ar₂ may be aromatic or heteroaromatic rings, wherein the heteroaryl means monovalent monocyclic or bicyclic aromatic radical of 5 to 10 ring atoms including pyridyl, pyrrolyl, pyrimidinyl etc. ,

Art Unit: 1617

which are meet the all the limitation herein defined except that n, as herein defined is 1, and the claimed compounds require n is 0. See pages 3-7. Those compounds are disclosed as useful pharmaceutical agent for treating CCR-3 receptor associated disorders, particularly, those eosinophil-mediated inflammatory diseases. See, the abstract, and pages 1-2, and the claims.

Rogers does not teach expressly the employment of the particular compound herein treating the eosinophilic disorders herein.

However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to use the compounds herein as CCR-3 receptor antagonist for treating the eosinophilic disorders herein.

A person of ordinary skill in the art would have been motivated to use the compounds herein as CCR-3 receptor antagonist for treating the eosinophilic disorders herein. Because the instant compounds are structural homologs of the reference compounds. One having ordinary skill in the art would have been motivated to prepare the instantly claimed compound because such structurally homologous compounds are expected to possess similar properties. It has been held that compounds that are structurally homologous to prior art compounds are prima facie obvious, absent a showing of unexpected results. In re Hass, 60 USPQ 544 (CCPA 1944); In re Henze, 85 USPQ 261 (CCPA 1950).

4. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rogers et al. (WO 0031032, IDS 02/23/2005), for reasons as set forth above, and in further view of Chen et al. (IDS 12/22/2004).

Rogers does not teach expressly the employment of CCR-3 receptor antagonist for treating AIDS.

Art Unit: 1617

However, Chen et al. teaches that CCR3 is a co-receptors for HIV-1 infection of microglia. The receptor promotes the efficient infection by HIV in CNS. See, particularly the abstract.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to use CCR3 receptor antagonist herein for treating AIDS patients

A person of ordinary skill in the art would have been motivated to use CCR3 receptor antagonist herein for treating AIDS patients because CCR3 antagonist would have been reasonably expected to slow the infection by HIV in CNS.

5. Claims 7, and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shiota et al. (WO 99/25686, IDS), in further view of Frade et al. .

Shiota teaches therapeutical compounds with a general formula essentially identical to the formula (I) herein employed (see, pages 7-20 in WO 99/25686). The general formula encompasses the particular species herein elected. See, particularly the claims, and the compounds disclosed therein. Shiota also disclosed that the compounds inhibit the action of chemokines such as MIP-1 alpha, and/or MCP-1 on target cells and are useful for treating various disorders associated with chemokine receptors, including asthma, Crohn disease, etc. See, particularly, page 1, and the claims.

Shiota does not teach expressly the particular species herein elected, the method of using the same for treatment of AIDS.

However, Frade et al. MCP-1 is a ligand of receptor CCR-2. (Applicants also admitted that the receptor tested in Shiota is CCR-2, see response filed October 14, 2004, page 28, first

Art Unit: 1617

paragraph). Frade et al. further disclosed that CCR3 receptor acts as co-receptor for HIV infection. See, particularly, the abstract. Frade et al. show the ability of monoclonal anti-CCR2 antibodies to interfere with HIV-1 replication. See, particularly, page 497 the right column.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to make the particular compound since the compound are within the general formula and Shiota teaches examples that structurally close to the elected species. See, compounds 243-247. Further, it would be obvious to one of ordinary skill in the art, at the time the claimed invention was made to use the particular compound, as CCR-2 receptor antagonist, for treating AIDS patients since CCR-2 receptor is known as co-receptor for HIV infection. As to the newly disclosed function, i.e., inhibiting CCR3, note the instant claims are directed to effecting a biochemical pathway with an old and well known compounds. The argument that such claims are not directed to the old and well-known ultimate utility (administering the compound to a subject having asthma) for the compounds, are not probative. It is well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to *In re Swinehart*, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical functions. The ultimate utility for the claimed compounds is old and well known rendering the claimed subject matter obvious to the

Art Unit: 1617

skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103.

Response to the Argument

Applicants' amendments and remarks submitted October 30, 2006 have been fully considered, but are not persuasive.

Applicants contend that the case law recited by the examiner, *In re Susi* 169 U.S.P.Q. 423 (CCPA) is out dated. Applicants further cite *In re Jones* and *In re Baird*, asserting the particular compound, even within the scope of the prior art, is not obvious. The arguments are not persuasive. First, the examiner does not share the view that *In re Susi* is outdated. At least the Office does not see *In re Susi* as outdated. See, MPEP 2123 II. Further, *In re Jones* and *In re Baird* are not applicable to the particular situation. *In re Jones*, the claim is directed to a particular salt, wherein the cation is an amine with ether moiety. The cited references there provide no direction to the amine cation. *In re Baird*, the particular bisphenol provide benefit not shared by others within the general formula. In instant case, *Roger et al.* teach all the limitation required herein for reaching the compounds, and there is no evidence that the compounds herein claimed possess any unobvious property.

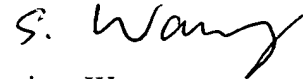
Shiota reference would have made the claimed invention obvious as new evidence (*Frade et al*) shows that CCR-2 is coreceptor of HIV infection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

Art Unit: 1617

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Shengjun Wang
Primary Examiner
Art Unit 1617

SHENGJUNWANG
PRIMARY EXAMINER